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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/678,595	Applicant(s) Wong et al.
	Examiner Hong Liu	Art Unit 1624

-- Th MAILING DATE of this communication appears on the c v r sheet with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-21 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-21 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claims 1-21 are pending in this application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following reason(s) apply:

The claims are not commensurate in scope as to the possibilities for the substituent "that sterically hinders access of the Pt atom to a DNA strand of a tumor cell" in the Z definition. The specification has no definition for "anion" for A, and, therefore, they are open-ended and all encompassing. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these broad claims, which embrace a diversity of anions and hetero rings at various locations on Pt.

In evaluating the enablement question, several factors are to be considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) the nature of the invention, 2) the state of the prior art, 3) the predictability of lack thereof in the art, 4) the

amount of direction or guidance present, 5) the presence or absence of working examples, 6)the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the invention in the instant application has claims which embrace a diversity of chemically and physically distinct compounds, wherein Z can be an unsubstituted or substituted, heteroaromatic group, containing one or more heteroatoms, etc. While a few compounds are disclosed, there is insufficient guidance for preparing additional antitumor which would be effective since the cited examples are drawn to a homogenous group of compounds not remotely commensurate in scope to applicants' claims. Only compounds wherein Z is imidazole, pyrazole, pyrazine, oxazole, and isoxazole have been made.

Furthermore, little testing data is provided for any of the compounds listed in the specification. Examples should be of sufficient scope as to justify the scope of the claim. However, the generic claims are much broader in scope than is represented by the testing. The definitions of the various A and Z variables on Pt embrace many structurally divergent groups not represented at all in testing, since testing for the instant compounds is not seen in the specification. Markush claims must be provided with support in the disclosure when the "working examples' fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms. See In re Fouch, 169 USPQ 429.

This area of activity can be expected to be highly structure specific and unpredictable, as is generally true for chemically-based pharmacological activity. In view of the structural divergence in the claims, one skilled in the art could not reasonably extrapolate the activities of some of the

claimed compounds to the other structurally divergent compounds embraced by the claims which have not been tested. In cases directed to chemical compounds which are being used for their physiological activity, the scope of the claims must have a reasonable correlation to the scope of enablement provide by the specification. See In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. No reasonable assurance has been made that the instant compounds as an entire class have the required activities needed to practice the invention. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability" have been demonstrated to be sufficiently lacking in the instant case for the scope being claimed.

Claims 21 is drawn to a method of treating cancer. However, it is unclear that platinum complexes are effective in treating all forms of cancer as Farrell et al. (US 5,624,919) point out that "critical problems still exist which limit the effective use of platinum complexes as therapeutics, most especially their narrow spectrum of activity against different tumors and the development of tumor cells which are resistant to the cytotoxic effects of cisplatin." Additionally, no evidence of in vitro/in vivo effectiveness is seen in the specification for one of the (let alone all) of the instant compounds for the uses claimed herein. See In re Surrey, 252 USPQ 724, regarding sufficiency of disclosure. Competent evidence of art-recognized efficacy for intended uses needs to be provided. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the likelihood of in vivo use for all uses being claimed. See Ex parte Powers, 220 USPQ 925.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1). Claim 1 is indefinite in that the metes and bounds of "ester", "carboxylate", "carbamate", and "bi-dentate carboxylate or sulfate" are unknown. There is no definition for these terms in the specification.

2). In claim 15, it is unclear which substituent can be coupled to the heterocycle and on which position of the heterocycle.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 9, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Wienkotter et al., Chem Abstract 126: 311303. The instantly claimed compounds read on the

reference compound, see the enclosed copy of CAPLUS computer search report and the compound having RN 161269-39-2. overcome

Claims 1-4, 6-11, 16, 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rochon et al., Chem Abstract 115: 269138. The instantly claimed compounds read on the reference compound, see the enclosed copy of CAPLUS computer search report and the compounds. overcome

Claims 1-3, 6, 7, 15, 16, 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by de Oliverira et al., Chem Abstract 125: 211928. The instantly claimed compounds read on the reference compound, see the enclosed copy of CAPLUS computer search report and the compound having RN 103436-53-9 and 116235-97-3. overcome

4. Claims 1-16 and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Skov et al. (US Patent 4,921,963). Skov teaches the compounds and composition of the instant invention (see Examples).

Claims 1-16 and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Murrer et al. (US Patent 5,665,771). Murrer teaches the compounds and composition of the instant invention (see Examples). Didn't overcome

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skov et al. (US 4,921,963). The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I, Col. 3 wherein X is an anion, L is selected from a substituted imidazole, pyrazole, thiazole, isothiazole, etc. The compounds are taught to be useful as anti-tumor agents. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, it would have nevertheless been obvious to one skilled in the art at the time of the invention to be motivated to select any of the species of the genus taught by the reference including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the specie of the genus would have similar properties and, thus, the same use as taught for the genus as a whole, i.e., antitumor agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. See *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murrer et al. (US 5,665,771). The reference teaches a generic group of compounds which embraces applicant's

instantly claimed compounds. See formula I, Col. 1 wherein A is leaving group, X is NH3, or mono- or di-alkyl substituted NH3. B is halo, hydroxy, carboxylate, carbamate, or carbonate ester, and Z is a substituted amine, etc. The compounds are taught to be useful as anti-tumor agents. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, it would have nevertheless been obvious to one skilled in the art at the time of the invention to be motivated to select any of the species of the genus taught by the reference including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the specie of the genus would have similar properties and, thus, the same use as taught for the genus as a whole, i.e., antitumor agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of

this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

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October 15, 2001

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